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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/656,934	09/05/2003	Kathleen Battista	PRD-39	6360

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EXAMINER	
DESAI, RITA J	
ART UNIT	**PAPER NUMBER**
1625	

DATE MAILED: 07/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/656,934	BATTISTA ET AL.	
	Examiner	Art Unit	
	Rita J. Desai	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-21 is/are pending in the application.

4a) Of the above claim(s) 14-21 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-13 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 4/21/04.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-13 in part , drawn to compounds and pharmaceutical compositions wherein R3 is an aryl, X is NR1R2, R1 and R2 are non –hetero ring containg. And the circle is a naphthyl, phenyl or acenapthyl. , classified in class 546, , subclass 18. A further election of example 438 on page 74 was elected for search purposes.

II. Claims 1-13 in part , drawn to compounds , pharmaceutical compositions , wherein R3, Ro and the circle are other than in group I . A further election of a single disclosed species is required, classified in various classes and subclasses.

III. Claims 14-19 , drawn to various methods of treating diseases, classified in class 514 and various subclass.

IV. Claims 20, 21 in part drawn to compounds of formula E , R3 is an aryl, Y is L'n is a circle and the circle is an aryl, classified in various classes and subclasses.

V. Claim 20 and 21 in part , drawn to compounds wherein R3, Y, and the circle are other than in group IV, classified in various classes and subclasses. A further election of a single disclosed species is required. This group may be subject to further restriction.

The inventions are distinct, each from the other because of the following reasons:

Inventions I, II, III, IV and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions

Invention I , II, IV and V are drawn to a different core structures and hence different properties.

If applicant 's traverse on the grounds that the inventions are not patentably distinct, applicants should submit evidence or identify such evidence now of record showing the groups to be obvious variants or clearly admit on the record that this is the case. In either instance if the examiner finds one of the inventions unpatentable over the prior art , the evidence or admission may be used in a rejection under 35 USC 103 of the other invention.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II-V , restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

If the compound claims are found to be allowable , examiner will rejoin a method claim limited to the same scope as the elected group.

During a telephone conversation with Mr. Hal Woodrow on 7/8/2004 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-13 in part . Affirmation of this election must be made by applicant in replying to this Office action. Claims 14-21 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for thiophene as a het group and substitutent, does not reasonably provide enablement for any and all the different heterogroup at the numerous and various positions. The specification does not enable any person skilled in the art to which it pertains, or with which it is

most nearly connected, to make and use the invention commensurate in scope with these claims. In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). .

The are many factors that need to be considered and amongst them are

The nature of the invention:- the invention is highly unpredictable . The activity of treating diseases is very unpredicatable. Caffeine and theophyline differ only in that , a hydrogen is replaced by a methyl group and the properties are so different.

The guidance provided by the applicants is very limited, from all the examples provided only thiophene as a hetero group has been taught.

Hetero groups are in a huge class and subclass of its own and have different properties, thus applicants do not have sufficient guidance for the use and making of the above compounds *without any undue burden.*

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-13 in part are rejected under 35 U.S.C. 103(a) as being unpatentable over

US 4329353 Stokbroekx et al

US 6043366 Adam et al.

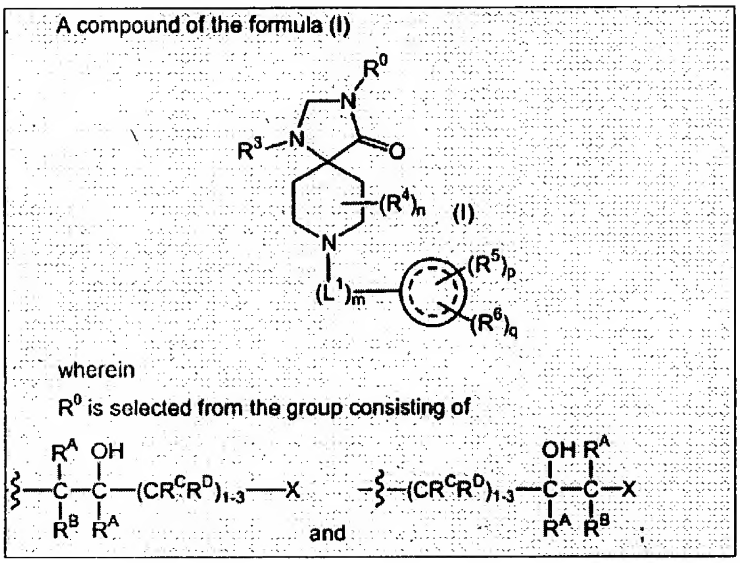
US 6277991 Hohlweg et al

US3839340 Scharpf.

WO 99/59997 Watson Brett and also

EP 0997464 A1 Ito Fumitaka et al

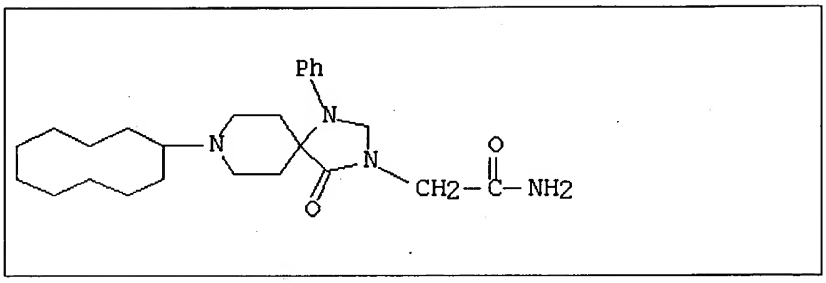
Applicants compounds are drawn to the formula



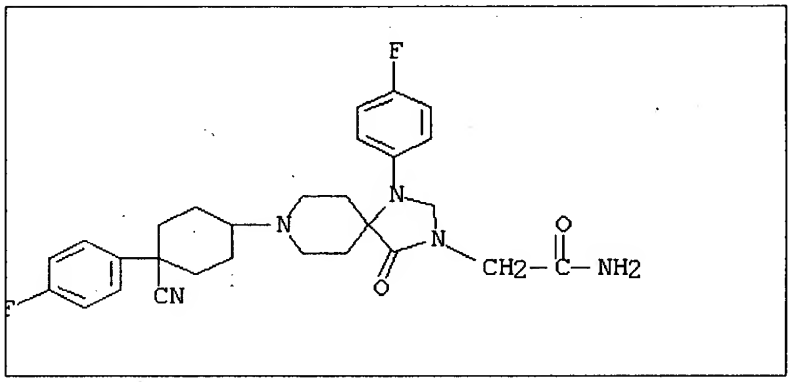
Wherein R3 is a aryl, X is N R8 R9, the circle is also a carbocylic non-hetero ring.

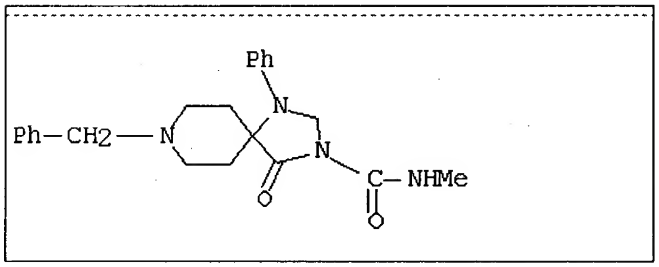
Determination of the scope and content of the prior art (MPEP §2141.01)

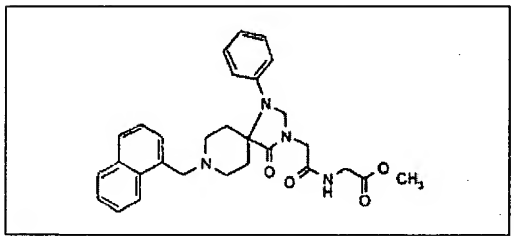
The above references all teach a similar core with R3 being an aryl, and the circle being a carbocylic ring .



The reference compounds also treat many of the same diseases.

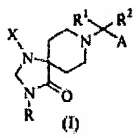






Wo 99/59997for inflammation, vasomotor disturbances .

EP 0997464 A1 Ito Fumitaka et al teaches the genus wherein R1 and r2 can form a ring , X is a phenyl and R is an alkyl or an amino alkyl which may be optionally substituted by



(I)

or its pharmaceutically acceptable salt, wherein

R^1 and R^2 are independently C_1-C_2 alkyl; or
R^1 and R^2, taken together with the carbon atom to which they are attached, form a mono-, bi-, tri- or spiro-cyclic group having 3 to 13 carbon atoms, wherein the cyclic group is optionally substituted by one to five substituents independently selected from halo, (C_1-C_3)alkyl, (C_2-C_3)alkenyl, (C_1-C_3)alkoxy, hydroxy, oxo, =CH_2 and =CH-(C_1-C_3)alkyl, provided that the bi- or tri-cyclic group is not a benzo-fused ring;
A is (C_1-C_7)alkyl, (C_2-C_6)alkenyl, (C_2-C_6)alkynyl, phenyl-(C_1-C_6)alkyl, phenyl or heteroaryl selected from furyl, thienyl, pyridyl and pyridyl, wherein the phenyl and heteroaryl are optionally substituted by one to three substituents selected from halo, (C_1-C_3)alkyl and (C_1-C_3)alkoxy;
R is hydrogen, (C_1-C_6)alkyl, (C_2-C_6)alkenyl, (C_2-C_6)alkynyl, (C_3-C_7)cycloalkyl, (C_1-C_6)alkanoyl, ((C_1-C_3)alkyl)-Z-(C_1-C_6)alkyl, (((C_3-C_7)cycloalkyl)-Z-(C_1-C_6)alkyl, heterocyclic-(C_1-C_6)alkyl, phenyl-(C_1-C_6)alkyl, heterocyclic-(C_1-C_6)alkyl-Z-(C_1-C_6)alkyl, phenyl-(C_1-C_6)alkyl-Z-(C_1-C_6)alkyl, heterocyclo-Z-(C_1-C_6)alkyl, (((C_3-C_7)cycloalkyl)-heterocyclo-(C_1-C_3)alkyl, heterocyclic-heterocyclic-Z-(C_1-C_6)alkyl, wherein the alkyl, alkenyl, alkynyl, cycloalkyl and heterocyclic are optionally substituted by one to three substituents selected from halo, hydroxy, amino, guanidino, carboxy, amidino, ureido, (C_1-C_3)alkyl, (C_1-C_6)alkoxy, and mono- or di-(C_1-C_6)alkylamino, and wherein Z is O, S, SO, SO_2, OO, C(=O)O, OC(=O), N(R), C(=O)N(R) or N(R)CO (preferred R in Z is hydrogen or (C_1-C_4)alkyl); and

OH.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The only difference is that the R0 has an =O instead of a hydroxide.

Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

A ketone and a hydroxide are tautomers of each other and hence it would have been obvious for one skill in the art to make the hydroxy compound .

Also the chain may have no alkyl chain.

The properties are however the same.

Applicants do not have any side by side comparison with the closest prior art to show any unexpected results.

EP 0997464 teaches the OH substitutent on the alkyl group. Thus there is a clear teaching that the compounds with an OH substituent would also retain its pharmaceutical properties, one would have found it obvious to make the modifications.

Conclusion

The claims 1-13 stand rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rita J. Desai whose telephone number is 571-272-0684. The examiner can normally be reached on Monday - Friday,9:30 am to 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Rita J. Desai
Primary Examiner
Art Unit 1625

7/16/04.

R.D.
July 15, 2004